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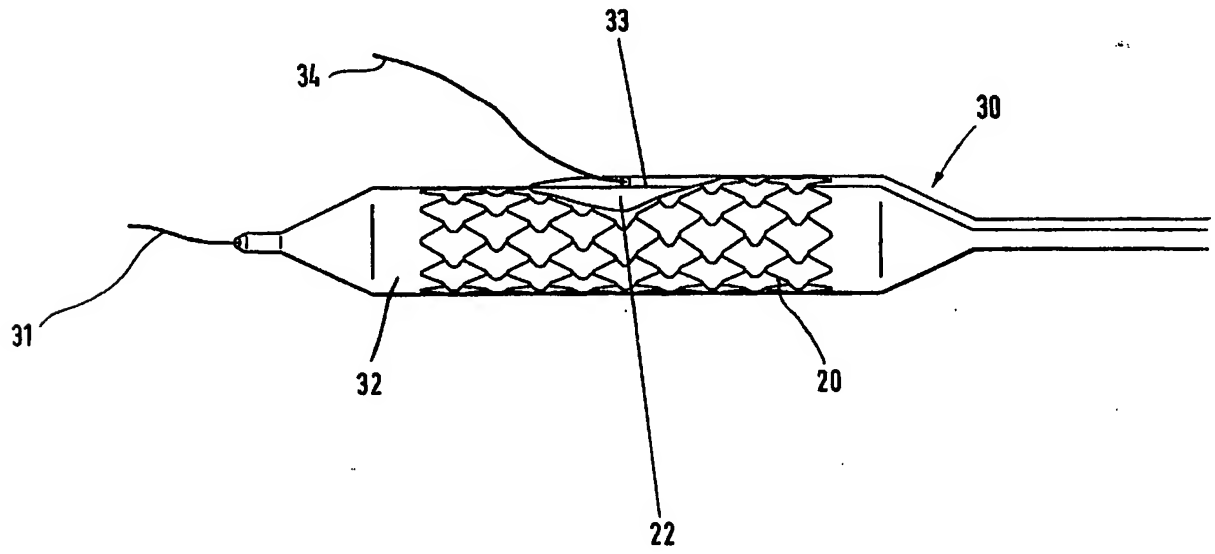
(54) Titre : STENT EXTENSIBLE RADIALEMENT DESTINE A ETRE IMPLANTE DANS UN VAISSEAU DE L'ORGANISME DANS LA REGION D'UNE RAMIFICATION VASCULAIRE

(54) Title: RADIALLY EXPANDABLE STENT FOR IMPLANTING IN A BODY VESSEL IN THE AREA OF A VASCULAR BRANCH



(57) Abrégé/Abstract:
An expandable stent for implanting in a body vessel in the area of a vascular branch, having an enlarged radial opening (22) which is premounted on a balloon catheter (30) for implanting in a vessel, whereby the balloon catheter (30) has a cavity (33) for leading through a guide wire (34) which protrudes from the cavity (33) and the stent (20) in the centre of the enlarged opening (22).

A b s t r a c t :

An expandable stent for implanting in a body vessel in the area of a vascular branch, having an enlarged radial opening (22) which is premounted on a balloon catheter (30) for implanting in a vessel, whereby the balloon catheter (30) has a cavity (33) for leading through a guide wire (34) which protrudes from the cavity (33) and the stent (20) in the centre of the enlarged opening (22).

Radially Expandable Stent for Implanting in a Body Vessel in the Area of a Vascular Branch

D e s c r i p t i o n :

The invention concerns a radially expandable stent for implanting in a body vessel in the area of a vascular branch in the form of a hollow cylindrical element. At narrow points in body vessels or body cavities, radially expandable stents are currently used to expand the narrowings and stabilize the vascular wall. Such narrowings of body vessels can thereby also occur in the area of vascular branches. The use of conventional stents is not possible in these cases, since their walls would hinder the free blood flow in the bifurcating vessel. In DE 297 01 758.6, a special stent was proposed which has a section with enlarged radial openings, so that this section may be placed over the bifurcation of the side branch vessel and the blood flow is no longer hindered or only slightly hindered. In a corresponding disadvantageous stenosis formation of the main vessel directly in the area of the bifurcation, however, this stent cannot adequately cover the diseased vascular section due to the large radial openings extending over an entire section.

Thus, it is the object of the present invention to create a stent which can be used in the area of vascular branches and thereby avoid the aforementioned disadvantages.

According to one aspect of the present invention, there is provided a device for implanting into a body vessel in the region of a vessel branching, comprising a radially expandable stent formed as a hollow cylindrical element and provided with an increased radial opening; and a balloon catheter on which the stent is premounted for implanting in the vessel, the balloon catheter having a first hollow chamber for passage of a first guiding wire so that it exits in a center of the increased opening from the first hollow chamber and the stent, the balloon catheter being provided with a second hollow longitudinal chamber extending along a longitudinal axis of the catheter and formed so that a second guiding wire extends through the second hollow longitudinal chamber and exits at a tip of the balloon catheter.

According to a further aspect of the present invention, there is provided a device for implanting into a body vessel in the region of a vessel branching, comprising a radially expandable stent formed as a hollow cylindrical element and provided with an increased radial opening, a balloon catheter on which the stent is pre-mounted for implanting in the vessel, the balloon catheter having a first hollow chamber and another longitudinal chamber extending along a longitudinal axis of the catheter, and guiding means including a first guiding wire passing through the first hollow chamber so that it exits in a center of the increased opening from the hollow chamber and the stent, and a further guiding wire extending through the other longitudinal chamber and exiting at a tip of the balloon catheter.

According to another aspect of the present invention, there is provided a stent of the aforementioned type which is characterized therein that it has an enlarged radial opening and is premounted on a balloon catheter for implanting in the vessel, whereby the

balloon catheter has a cavity for leading a guide wire through which protrudes from the cavity and the stent in the centre of the enlarged opening. Due to the fact that there is only one enlarged opening in the stent wall which can be placed directly over the bifurcation point, it is ensured that the entire vascular wall is securely supported by the stent. In this case, the enlarged opening has the function of ensuring the unhindered blood flow into the side branch vessel. However, to accurately position this stent, appropriate aids are absolutely necessary. Solely due to the use of X-ray contrast media, it is not possible to accurately position the one enlarged opening over the bifurcation. For this reason, the stent of the invention is premounted on a balloon catheter which has a cavity for a guide wire that passes through the enlarged opening. With aid of this guide wire, it is possible to accurately position the large opening of the stent over the decline of the side vessel. For this purpose, the catheter is manipulated by turning and shifting while adding X-ray contrast media and visual observation on the fluorescent screen until it is possible to insert the second guide wire into the side branch vessel. To insert the balloon catheter into the main vessel, the balloon catheter can have a cavity extending in a known manner along its longitudinal axis for a first guide wire projecting from the tip of the balloon catheter. It can be pushed ahead to the vascular bifurcation without difficulty along this guide wire before the enlarged opening is exactly positioned with aid of the second guide wire. After it is ensured that the catheter is accurately positioned, the balloon is blown up and the stent adjoins the vascular wall. The catheter can then be removed again from the vessel along the two guide wires. The stent remains with the two wires in the vessel. A further balloon catheter can be inserted into the branch via the guide wire of the side

branch vessel, in order to again expand the enlarged opening, if necessary. It can thus be ensured that no part of the wall of the stent can hinder the blood flow in the side branch vessel. The balloon catheter can be designed in various ways. Thus, the cavity for the guide wire led out of the enlarged opening can be formed by fastening a tubule on the balloon surface. However, this cavity may also be formed by the intermediate space in a double-walled balloon. Placing an expandable hose piece over the balloon is also possible in order to create a cavity between this piece of hose put on and the balloon for the guide wire. In an alternative embodiment, the balloon catheter can have three coaxially arranged hoses, whereby the two inner hoses form cavities for accommodating the two guide wires.

The stent itself can also be made in various ways. It can have a multicellular wall and be made from a tube. But it is also possible to make the stent from wire. It can thereby be bent, braided, knitted or woven. Advantageously, the enlarged opening can be placed in the middle of the stent, however, an eccentric arrangement of the enlarged opening may also be realized for certain applications.

A preferred embodiment of a stent according to the invention shall be described in greater detail in the following with reference to the drawings, showing:

Fig. 1 three schematical representations of vascular branches with stenoses;

Fig. 2 a representation of the surface structure of a stent according to the invention;

Fig. 3 a side view of a stent premounted on a balloon catheter.

Fig. 1 shows three examples of typical stenoses as can occur at vascular bifurcation points. In Fig. 1a, the stenosis 12 is in the main vessel 10 in front of the bifurcation of a side branch vessel 11. In Fig. 1b, there is a very large stenosis 12' directly opposite the bifurcation point of the side branch vessel 11 and in Fig. 1c in the transition between main vessel 10 and side branch vessel 11. Especially the stenosis according to Fig. 1b can only be inadequately covered with a bifurcation stent having a section with enlarged radial openings. A stent according to the invention, as shown in Figs. 2 and 3, is suitable for just such cases. Fig. 2 shows the surface structure of a stent 20 which has a number of diamond-shaped radial openings 21 in the expanded state. In the central area of the stent 20, a single, very large diamond-shaped opening 22 is formed which, in a body vessel, can be placed exactly over the bifurcation of a side branch vessel 11 (Fig. 1). To enable the accurate positioning of the stent 20, it is premounted on a balloon catheter 30, as shown in Fig. 3. The balloon catheter 30 shown in Fig. 3 has, in its interior, a cavity (not shown in greater detail) for leading through a first guide wire 31. A stent 20 is mounted in the area of a balloon 32 of the catheter 30. Moreover, a further cavity 33 extends into the area of the balloon 32 for leading through a second guide wire 34 which protrudes from the cavity 33 and the stent 20 in the area of the enlarged opening 22. This guide wire 34 is inserted into a side branch vessel 11 and thus serves as an adjustment aid for positioning the stent 20 in a body vessel 10. In addition, after the balloon catheter 30 has been pulled out of the vessel 10, it can be used as a guide wire for a further balloon catheter to

expand the enlarged opening 22. The embodiments of the balloon catheter 30 shown, as well as the stent 20, are merely by way of example. The cavity 33 required for leading through the second guide wire 34 can, for example, also be formed by a double-walled balloon 32 or two coaxial hose pieces. The stent 20 shown is cut from a tubule; however, it can also be bent, knitted, twisted or woven.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A device for implanting into a body vessel in the region of a vessel branching, comprising a radially expandable stent formed as a hollow cylindrical element and provided with an increased radial opening; and a balloon catheter on which said stent is premounted for implanting in the vessel, said balloon catheter having a first hollow chamber for passage of a first guiding wire so that it exits in a center of said increased opening from said first hollow chamber and said stent, said balloon catheter being provided with a second hollow longitudinal chamber extending along a longitudinal axis of said catheter and formed so that a second guiding wire extends through said second hollow longitudinal chamber and exits at a tip of said balloon catheter.

2. The device as defined in claim 1, wherein said stent is dilatable so that after a dilation of said stent, said balloon catheter is pullable along said guiding wires out of the vessel.

3. The device as defined in claim 1 or 2, wherein said first guiding wire is guided through said first hollow chamber out of said increased opening.

4. The device as defined in any one of claims 1 to 3, wherein said balloon catheter has a balloon portion, said first hollow chamber for said first guiding wire guided out of said increased opening being formed by a pipe mounted on an outer surface of said balloon portion of said catheter.

5. The device as defined in claim 3, wherein said catheter has a balloon portion which is formed as a double-walled balloon, said first hollow chamber for guiding said first guiding wire from said increase opening being formed as an intermediate chamber of said double-wall balloon.

6. The device as defined in claim 3, wherein said balloon catheter has a balloon portion, said first hollow chamber for guiding said first guiding wire out of said increased opening being formed as an intermediate chamber between said balloon portion and a stretchable hose piece which is pulled onto said balloon portion.

7. The device as defined in any one of claims 1 to 3, wherein said balloon catheter is composed of three coaxial hoses arranged so that two inwardly located hoses form said hollow chambers for receiving said guiding wires.

8. The device as defined in any one of claims 1 to 7, wherein said stent is composed of a pipe and has a multi-cellular wall.

9. The device as defined in any one of claims 1 to 7, wherein said stent is bent from a wire.

10. The device as defined in any one of claims 1 to 7, wherein said stent is formed as a wire selected from the group consisting of structured wire, knitted wire and twisted wire.

11. The device as defined in any one of claims 1 to 10, wherein said increased opening is arranged in a center of said stent.

12. The device as defined in any one of claims 1 to 10, wherein said increased opening is arranged eccentrically on said stent.

13. A device for implanting into a body vessel in the region of a vessel branching, comprising a radially expandable stent formed as a hollow cylindrical element and provided with an increased radial opening; a balloon catheter on which said stent is pre-mounted for implanting in the vessel, said balloon catheter having a first hollow chamber and another longitudinal chamber extending along a longitudinal axis of said catheter; and guiding means including a first guiding wire passing through said first hollow chamber so that it exits in a center of said increased opening from said hollow chamber and said stent, and a further guiding wire extending through said other longitudinal chamber and exiting at a tip of said balloon catheter.

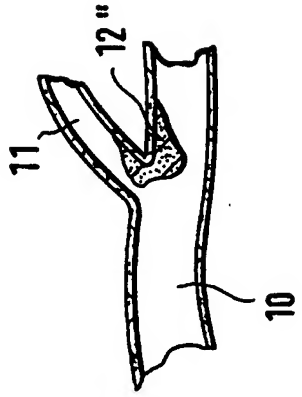


FIG. 1c

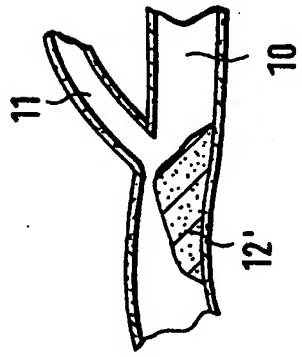


FIG. 1b

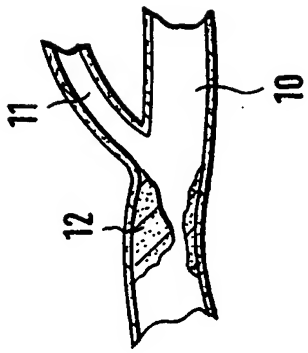


FIG. 1a

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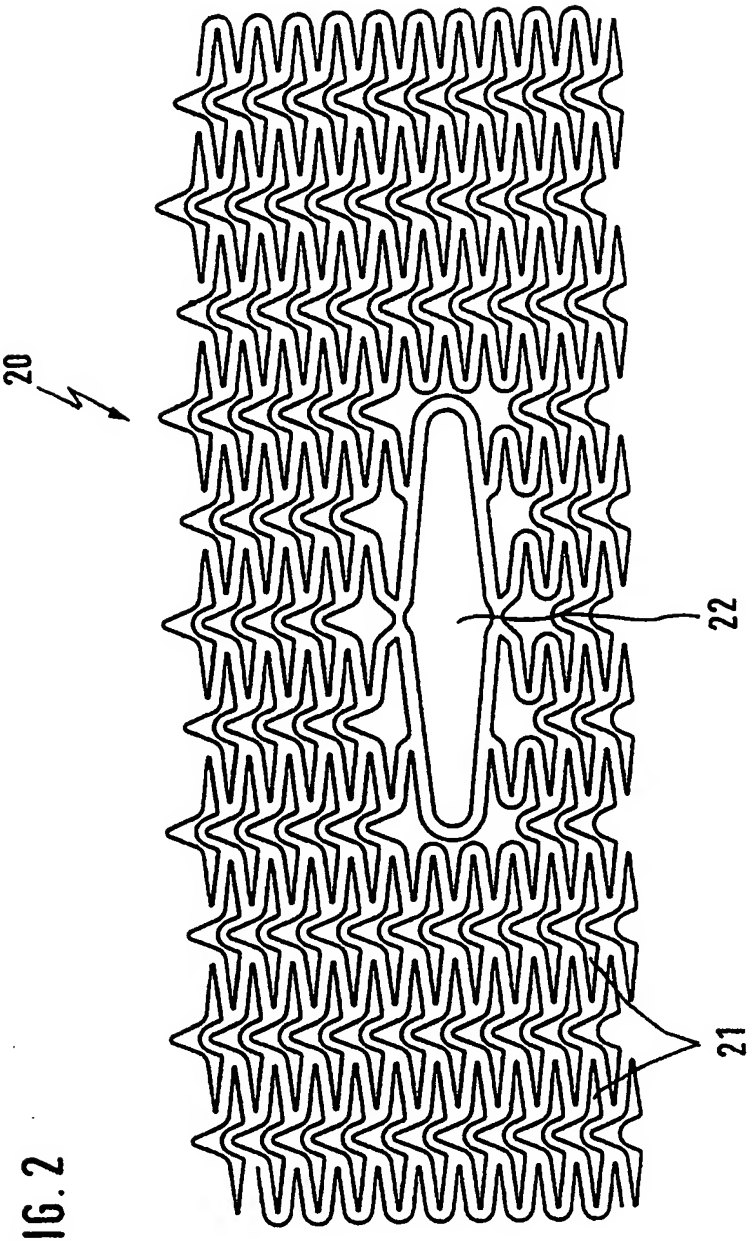

FIG. 2

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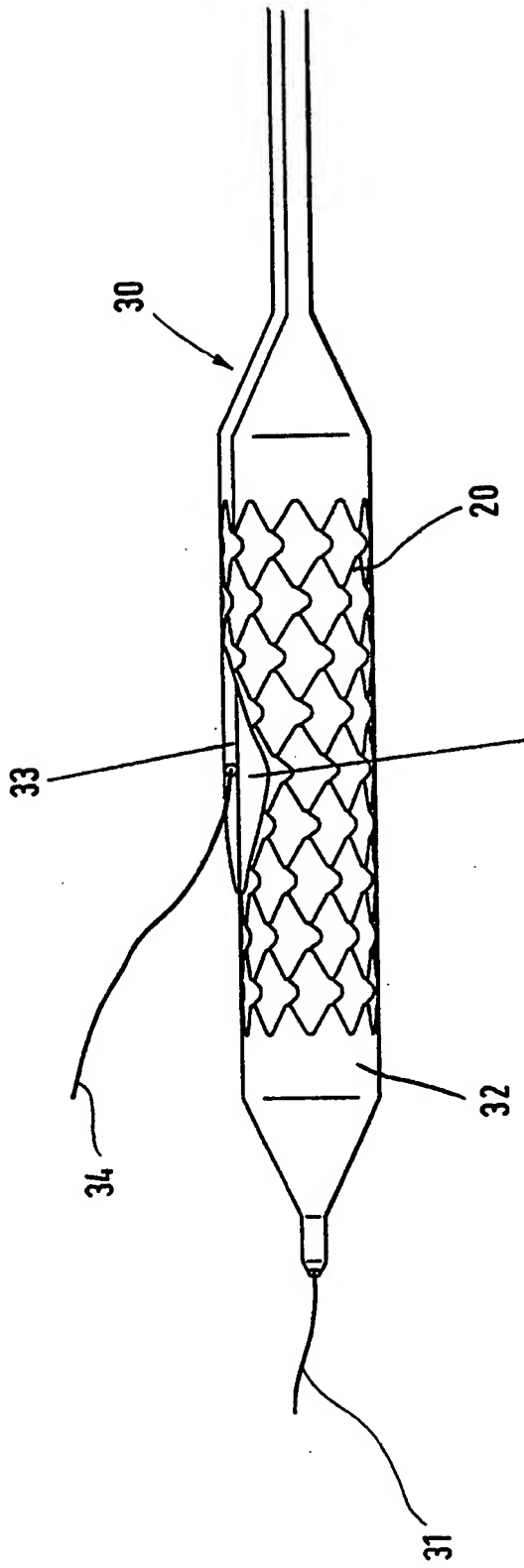

FIG. 3

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